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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,204	01/27/2004	Yuzhang Wu	32209-728.201	3325
21971 7590 06/27/2008 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050				
EXAMINER SIEFKE, SAMUEL P				
ART UNIT 1797		PAPER NUMBER		
MAIL DATE 06/27/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/766,204

Applicant(s)

WU ET AL.

Examiner

SAM P. SIEFKE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,14-18,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 3,7,8,19-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date 3/10/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 depends from claim 3 which claims a slot that extends through a cap and communicates with the fluid segregation chamber.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 recites the limitation "the plunger housing." There is insufficient antecedent basis for this limitation in the claim. The Examiner recommends that claim 16 depend from claim 15 which would provide proper antecedent basis for this limitation.

Claim 22 recites the limitation "the plunger housing." There is insufficient antecedent basis for this limitation in the claim. The Examiner recommends that the claim depend from claim 4 which would provide proper antecedent basis for the this limitation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 14-18 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Guirguis et al. (USPN 6,277,646).

Guirguis discloses a fluid specimen collecting and testing apparatus the comprises a collection chamber (40) a plunger (100, fig. 1-3 and 9, col. 7, lines 21-24) movably positioned within the container that moves from a first position (fig.1) to a second position (fig. 2); a test chamber 80 (fluid segregation chamber) that receives a portion of the fluid specimen from the container, wherein the fluid in the test chamber is segregated from the fluid in the container by wall 50 and 55; an isolation chamber (fluid flow lumen) that provides passageway for a portion of the fluid specimen to flow into the test chamber, wherein a first end of the passageway has a first opening (located at ref. 75 in fig. 1) that opens into the test chamber 80 and a second opening (located at ref. 70 in fig. 1) configured to receive a portion of the fluid specimen from the collection chamber; a seal member (75, fig. 7, col. 7, lines 7-20) that covers the first opening, the seal member prevents the fluid from flowing into the test chamber until the seal member is broken (col. 7, lines 7-21); the plunger is configured to move from a first position (fig. 1) to a second position (fig. 2) upon coupling of a lid (20) to break the seal member and further cause a portion of the fluid specimen to flow through the second opening into the

isolation chamber and out of the first opening into the test chamber (col. 8, lines 12-36). Regarding the test element, the Examiner states the test element is not positively recited in the claim nor has any relationship between the test element and the rest of the device been claimed. The claim only recites a plunger that is configured to move from a first position to a second position. Regarding claim 18, test elements (95) are provided in the test chamber (80).

Regarding claim 4 and 15, Guirguis discloses a plunger housing (partially made by the isolation chamber with the plunger) that extends downwardly from the cap into the container. The Examiner states that the claim does not require the plunger housing to be attached to the cap, just that the plunger housing extend downwardly from the cap. The plunger housing (isolation chamber with plunger therein) is below the cap when the cap is rested on the container (fig. 1) and when the cap is coupled to the container the cap touches the plunger housing (see fig. 2). Therefore, the plunger housing extends downwardly from the cap into the container. The plunger housing further comprises sidewalls and a bottom wall (fig. 1-3).

Regarding claim 5 and 16, a reservoir chamber is located within the lower region of the plunger housing (isolation chamber) and has a fluid entry port (fig. 3, opening located below ref. 3) located in the side wall of the plunger housing through which a portion of the fluid specimen flows into the reservoir chamber from the container.

Regarding claim 6 and 17, the second opening (70) of the isolation chamber opens into the reservoir chamber, and wherein at least a portion of the plunger blocs fluid from flowing into the fluid entry port when the plunger moves from the first position

toward the second position such that fluid in the reservoir chamber flows into the flow lumen as the plunger moves toward the second position (col. 7, lines 34-39).

Regarding claim 22 and 23, the Examiner states that the plunger housing creates a plunger shaft because the housing is cylindrical and the plunger takes the shape of the shaft so it slides smoothly within the shaft.

### ***Allowable Subject Matter***

Claims 3, 7-8, 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 3, the prior art does not teach or fairly suggest a slot that extends through the caps and communicates with the segregation chamber. Regarding claim 7 and 19, the prior art does not teach or fairly suggest a fluid flow lumen being located with a plunger. Regarding claim 8, the prior art does not teach or fairly suggest the plunger housing is removably attached to the cap. Claim 21 is dependent on claim 3.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/  
Primary Examiner, Art Unit 1797

June 19, 2008